



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT EXAMINING OPERATION

In re Application of: § Atty Docket No.: PISA,015
Madhavan PISHARODI §
§
Serial No.: 10/804,895 § Group Art Unit: 3774
§
Filed: March 19, 2004 §
§
For: ROTATING, LOCKING, § Examiner: P. Prebilic
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CERTIFICATE OF MAILING (37 C.F.R. 1.8a)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date indicated below with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313.

Aug. 19, 2008
Mark R. Wisner, Registration No. 30,603 Date

RESPONSE TO OFFICIAL ACTION OF NOVEMBER 19, 2008

Dear Sir:

Applicant responds to the Official Action mailed in the captioned application on November 19, 2008 as follows. Also enclosed is a Request for Continued Examination. Applicant filed a Notice of Appeal (with a request for a three-month extension of time and the required fees) in the application on May 19, 2008 and encloses (1) a request for an extension of time for one month (beyond the two-month period for filing an appeal brief after a notice of appeal) and (2) the fees for the extension of time and the request for continued examination along with this Response.

In the event any check or authorization to charge credit card in the amount of any necessary fees was not properly executed, was not included with this Response and/or was insufficient in amount, or for any other reason this Response is not considered timely filed, request is hereby made for an extension of the time for the period necessary to ensure consideration of this Response and the Commissioner is authorized to charge Deposit Account No. 50-0965 (PISA,015) in the amount of any necessary fee.

IN THE CLAIMS

Please amend and/or cancel the claim(s) of the captioned application, and/or add claim(s) to the application, in accordance with the following annotations and/or mark-ups showing all change(s) relative to the previous version(s) of the claim(s) as required by 37 C.F.R. 1.121:

1. (Withdrawn) A stabilizer for implanting in the disk space between adjacent vertebrae of a patient to stabilize the vertebrae comprising:

an elongate implant having a substantially rectangular cross-sectional shape;

a lock having a bearing surface formed thereon for mounting to one end of said implant with the bearing surface of said lock contacting an adjacent vertebrae to resist rotation of said implant in the disk space; and

an insert mounted to and biased away from said implant and into engagement with an adjacent vertebra.

2. (Currently amended) A method of cushioning between an elongate implant that is positioned in a space from which a portion of an intervertebral disk has been removed and the vertebra adjacent the disk space, the implant having a substantially rectangular cross-sectional shape and a height that is greater than the width of the implant, comprising the steps of:

inserting the implant into the intervertebral disk space with the sides of the implant defining the height of the implant in contact with the adjacent vertebra, the implant being provided with having an insert that is mounted thereto on a spring and movable relative to the implant;

rotating the implant along the longitudinal axis thereof so that the sides of the implant defining the width of the implant contact the adjacent vertebra; and

biasing the insert away from the implant against the adjacent vertebra with the spring.

3. (Withdrawn) A stabilizer for insertion into a space between two adjacent vertebrae comprising:

an implant;

an insert mounted to and movable with respect to said implant;

means between said insert and said implant for biasing said insert away from said implant and into contact with an adjacent vertebrae when said implant is inserted into a space between two adjacent vertebrae; and

a lock for mounting to said implant and having a surface formed thereon for bearing against one or both of the adjacent vertebrae to resist rotation of said implant relative to the adjacent vertebrae.

Claims 4-10. (Canceled)

11. (Withdrawn) A stabilizer for insertion into a space between two adjacent vertebrae comprising:

an implant;

an insert mounted to said implant, said insert being comprised of a springy material that is initially compressed for insertion into a space between two adjacent vertebrae and then released from the initial compressed state into engagement with an adjacent vertebra; and

a lock for mounting to said implant and having a surface formed thereon for bearing against one or both of the adjacent vertebrae to resist rotation of said implant relative to the adjacent vertebrae.

Claims 12-18. (Canceled)

19. (Currently amended) A method of stabilizing two vertebrae comprising the steps of:

removing a portion of the intervertebral disk of a patient;

inserting an implant having an insert movably mounted thereto into the space from which a portion of the intervertebral disk has been removed;

biasing the movable insert into engagement with a vertebra adjacent the intervertebral disk space; and

resisting rotation of the implant relative to the adjacent vertebra along the longitudinal axis thereof.

20. (Previously presented) The method of claim 19 additionally comprising filling any space between the implant and the two vertebrae with a hydrogel.

21. (Previously presented) The method of claim 20 wherein said hydrogel is selected from the group consisting of protein polymers, polyvinylpyrrolidone polymers, and modified collagen matrix.

22. (Previously presented) The method of claim 20 additionally comprising contacting the remaining portion of the intervertebral disk, or the hydrogel, or both the remaining portion of the intervertebral disk and the hydrogel with a medical grade adhesive.

23. (Previously presented) The method of claim 19 additionally comprising sealing the intervertebral disk space with a medical grade polymer.

24. (Previously presented) The method of claim 19 wherein the insert comprises a metal or other relatively incompressible material and is biased away from the implant into engagement with the adjacent vertebra by a spring.

25. (Previously presented) The method of claim 24 additionally comprising restraining the insert against movement relative to the implant until after the implant is inserted into the intervertebral disk space from which a portion of the intervertebral disk has been removed.

26. (Previously presented) The method of claim 19 wherein the implant comprises a metal or other relatively incompressible material and the insert comprises a springy, compressible material that provides a cushioning effect when engaged by the adjacent vertebrae.

27. (Previously presented) The method of claim 26 additionally comprising compressing the insert before inserting the implant and insert into the intervertebral disk space from which a portion of the intervertebral disk has been removed and then releasing the insert from the initial, compressed state into engagement with the adjacent vertebra.

28. (Previously presented) The method of claim 2 additionally comprising restraining the insert against movement relative to the implant until after the implant is inserted into the intervertebral disk space from which a portion of the intervertebral disk has been removed.

29. (Previously presented) The method of claim 2 wherein the implant comprises a metal or other relatively incompressible material and the insert comprises a compressible material that provides a cushioning effect when engaged by the adjacent vertebrae.

30. (Previously presented) The method of claim 29 additionally comprising compressing the insert before inserting the implant into the intervertebral disk space from which a portion of the intervertebral disk has been removed and then releasing the insert from the initial, compressed state into engagement with the adjacent vertebra.

31. (Previously presented) The method of claim 2 additionally comprising maintaining alignment of the implant and the insert while biasing the insert away from the implant.

32. (Previously presented) The method of claim 2 additionally comprising resisting rotation of the implant in the intervertebral disk space.

33. (Previously presented) The method of claim 2 additionally comprising limiting the movement of the insert away from the implant.

34. (Previously presented) The method of claim 2 additionally comprising resisting movement of the implant out of the intervertebral disk space.

35. (Previously presented) The method of claim 19 additionally comprising comprising resisting movement of the implant out of the intervertebral disk space.

REMARKS

The Official Action of November 19, 2007 objected to claims 2, 19, and 29-35 for certain informalities noted on page 2 of the Action. Claims 19 and 24-27 were rejected under 35 U.S.C. 102 as being anticipated by the Perren, *et al.* patent ("Perren"). Claims 2, 28, 29, and 31-35 were rejected under §102(b) as being anticipated by the Sertich patent ("Sertich"). Claims 19-21, 24, and 26 were rejected under 35 U.S.C. 103 as being obvious over the combination of the Ralph '731 or '291 patents in view of Muhanna, and claims 22-23 were rejected under that same section of the Statute as being obvious over the combination of the two Ralph patents and Muhanna in view of the Haldemann patent. Claim 30 was also rejected under §103 over the combination of Sertich and the Pisharodi '926 patent. All of these objections/rejections are traversed, and in accordance with the requirements of 37 C.F.R. 1.111(b), the basis for traversing these rejections is set out below.

With regard to the informality that prompted the objection to claim 2, Applicant has not amended claim 2 because the allegedly offending language is not included in claim 2. This same informality was noted, and claim 2 was objected to, in the June 7, 2006 Official Action. In response to that objection, Applicant removed that language from claim 2 such that renewal of the same objection in the Official Action of November 19, 2007 appears to be an inadvertent error. Reconsideration and withdrawal of the objection is therefore respectfully requested.

Nor has Applicant amended claims 19 or 32-35 in response to the objection to the word "resisting" in those claims. Applicant appreciates the suggestion in the Official Action that claims 19 and 32-35 characterize a feature of the implant and certainly agrees that the present invention provides functions and advantages that are not, so far as is known, provided by prior art vertebral stabilizers. However, Applicant deliberately chose to define this step of the invention without regard to structure in contemplation of different ways that rotation of the implant can be resisted. For instance, rotation can be resisted by packing the intervertebral space with bone chips or in the manner explained at page 13, lines 25 *et seq.* of the specification of the captioned application. Reconsideration and withdrawal of this objection to claims 19 and 32-35 is respectfully requested in light of this explanation.

With regard to the objection to claims 29-31, the words "maintaining" and "biasing" do not appear in claims 29-30, so reconsideration and withdrawal of the objection to those claims, and/or some additional explanation as to the basis for the objection, is respectfully requested. Those words do appear in claim 31, and that claim uses the word "biasing" because the claim depends on claim 2 and the third step of claim 2 recites the step of "biasing" such that it is submitted that it is entirely appropriate to use that word in claim 31 (stated another way, claim 2

provides antecedent basis for the use of that word in claim 31). The word "maintaining" is an additional element introduced into claim 31 that was deliberately chosen by Applicant to define that step in the method without regard to any structure used to implement the step of maintaining alignment while biasing the insert away from the implant. Structure for maintaining alignment is described/shown at page 8, lines 24 *et seq.*, at reference numerals 62, 64 in Fig. 3, and elsewhere throughout the captioned application. That structure, and other structure not described in the application but that may be implemented by those skilled in the art who have the benefit of the instruction provided by the application, is intended to be covered by this recitation of the step of maintaining alignment. Reconsideration and withdrawal of the objection to claim 31 is respectfully requested in light of these remarks.

In reviewing the application history relating to the §102 rejection of claim 19 over Perren, Applicant discovered that some clarification and explanation may be in order. First, the basis for this rejection was explained in the section of the June 5, 2007 Official Action titled "Response to Arguments," and Applicant's Response to that June 5, 2007 Action indicated (in the middle of page 8) that Applicant had amended claim 19 to recite that **only** a portion of the intervertebral disk is removed. However, it turns out that Applicant did not amend claim 19 in this fashion in the Response to Official Action of June 5, 2007. With "20/20 hindsight," and for the following reason, it is probably a good thing that the claim was not amended in this manner. In defining over Perren, Applicant argued (starting at the middle of page 7 of Applicant's Response to Official Action of January 8, 2007) that Perren discloses removal of the entire intervertebral disk. In reviewing Perren, however, it was found that the specification of that patent refers to "total or partial replacement of the disk from between the vertebrae" (col. 1, lines 25-26), words that neither Applicant nor Applicant's counsel spotted when making the remarks set out in Applicant's Response to Official Action of January 8, 2007. In spite of that language, Applicant is not going to retract that argument at this time because even though Perren appears to suggest removing all or a part of the intervertebral disk, a review of the structure of that device, as well as the language that appears at col. 1, lines 8-11 of Perren (cited in Applicant's Response to Official Action of January 8, 2007), makes it clear that Perren contemplates removing the entire disk (*see*, for instance, col. 2, lines 37-39 of Perren, which reads: "FIG. 1 shows a surgical prosthetic device adapted for placement between two adjoining vertebrae **after removal of the disk from therebetween** [emphasis added]."). Instead of retracting Applicant's argument, and after pointing out that it is a difference between Applicant's claimed invention and the device disclosed in Perren, Applicant will simply not rely on this difference in pointing out how claim 19 defines over Perren (please note that Applicant is not waiving the opportunity to make

arguments as to how Perren does not disclose removing a portion of the disk; instead, Applicant is choosing not to rely on that argument in this Response).

Having (hopefully!) clarified this point, Applicant directs attention to the last element of claim 19, reciting that rotation of the implant relative to the adjacent vertebrae is resisted. No such disclosure is found in Perren (nor does the Official Action of November 19, 2007 even allege that such disclosure is found in Perren). There are other differences between the device disclosed in Perren and Applicant's claim 19. For instance, claim 19 recites that an insert that is movably mounted to the implant is biased away from the implant, and although (as suggested at the top of page 3 of the Action) Perren may disclose two plates that are movable relative to each other, there is no disclosure in Perren of biasing one plate away from the other. Instead, as noted in the Action, the plates 1, 2 disclosed in Perren are spaced apart by means 4 that causes one or the other of the plates 1, 2 of that device to return to the initial, spaced apart position (see the description in col. 1, lines 31-35 of Perren of the use of shape-memory alloys (SMA) for the connecting wires 4 of that device) **after the device is compressed between adjacent vertebrae**. It is respectfully submitted that there is a difference between structure that causes two plates to try to return to their original, spaced apart position (the SMA connecting wires 4 of Perren) and the claimed structure, which effectively calls for a device that changes shape in the sense that an insert is initially mounted to the implant and restrained from movement to facilitate inserting the implant into the disk space and the insert is then released and biased away from that restrained position (as described, for instance, at pages 8-9 of the specification of that captioned application). Reconsideration and withdrawal of the §102 rejection of claim 19 over Perren is respectfully requested in light of the differences between claim 19 and Perren.

Because they are dependent upon a main claim that is not anticipated by Perren, claims 24-27 are also allowable. In addition, each of claims 24-27 recites subject matter that is not disclosed in Perren. For instance, because Perren does not disclose an insert mounted to and biased away from an implant, it cannot disclose a spring for biasing an insert away from an implant as recited in claim 24 or restraining an insert until after an implant is inserted into the disk space as recited in claim 25. Similarly, Perren does not disclose an insert comprised of a springy, compressible material as recited in claim 26. Nor does Perren disclose compressing an insert and then releasing the compressed insert after an implant has been inserted into the disk space as recited in claim 27. Reconsideration and withdrawal of the §102 rejection of claims 24-27 is respectfully requested in light of these differences between the claims and Perren.

Turning now to the §102 rejection of claims 2, 28, 29, and 31-35 over Sertich, claim 2 was amended to recite structure that was believed to be inherent (such that the amendment

should not be required to define over Sertich), but is now called out explicitly. Applicant made this amendment to point out how claim 2 already defined over Sertich and to clarify that the insert is mounted on a spring and that it is the spring that biases the insert away from the implant. Sertich discloses no such structure. Indeed, it is questionable whether the action of the piston 114 of the device described in that patent, which forces the peg 70 out of implant 30, can even be accurately characterized as "biasing" the peg 70 away from the implant. The device disclosed in Sertich certainly does not allow pegs 70 to move both away from and toward implant 30 and, although claim 2 recites only that the insert is biased away from the implant (such that it does not require such movement), it should be clear from the use of the term "bias" in claim 2 that Applicant contemplates that the insert can also move toward the implant. Nevertheless, Applicant amended claim 2 to clarify this difference between that claim and the Sertich patent. Reconsideration and withdrawal of the rejection of claim 2 is therefore respectfully requested.

Each of claims 28, 29, and 31-35, being dependent upon an allowable main claim, is likewise allowable. In addition, those claims introduce additional subject matter not disclosed in Sertich such that they are each separately allowable. For instance, Sertich does not disclose the step of restraining an insert against movement as recited in claim 28 or, despite the allegation in the Action that no material is perfectly rigid, "a compressible material that provides a cushioning effect" as recited in claim 29. With regard to this latter difference, Applicant is willing to concede that if you smash it hard enough, any material will compress, but Applicant is not claiming a hammer mill or an automated riveting machine. Applicant's invention (as set out in the preamble of claim 2 on which claim 29 is dependent) is a method of cushioning between adjacent vertebrae, and it is well known that when bone bears against metal, the bone fails, not the metal. It is therefore respectfully submitted that the allegation that no material is perfectly rigid is of little relevance in the context of Applicant's claim 29. Nor does Sertich disclose limiting the movement of an insert as recited in claim 33. Other differences can likewise be listed, but it is clear that there are differences such that the reconsideration and withdrawal of the rejection of claims 28, 29, and 31-35 is respectfully requested.

The §103 rejection of claims 19-21, 24, and 26 is virtually the same rejection as was made in three previous Office Actions and is again respectfully traversed. Applicant previously noted that none of the cited references teach a method involving removal of only a portion of the disk, and in response to that argument, the November 19, 2007 Action noted that the claims use open-ended claim language and do not include the word "only" (i.e., "removing only a portion of the disk") such that the claims allegedly still read on the cited references. Applicant respectfully disagrees since it is clear from each of the cited references that they are intended for use as

replacement disks, not as an insert into the disk space, but putting that issue aside, these claims are also allowable because neither Ralph nor the other cited patents teach or suggest resisting rotation of the implant along the longitudinal axis of the Implant as recited in the last element of claim 19 as amended. Reconsideration and withdrawal of the §103 rejection of claim 19 over the combination of the Ralph and Muhanna patents is respectfully requested in light of this clarifying amendment.

All of claims 20, 21, 24, and 26 are dependent on an allowable main claim and are therefore likewise allowable, but those claims also introduce additional limitations not disclosed in the cited art. For instance, with regard to the rejection of claims 20-21, Applicant takes issue with the allegation near the bottom of page 4 of the Action that Muhanna discloses an implant that is similar to the implant disclosed in the Ralph patents. The two implants are very different in structure and function, and it is therefore respectfully suggested that one skilled in the art would not be motivated to combine the two references. Note also that the Action alleges that it would have been obvious to fill the space around the Ralph implants with collagen gel when in fact Muhanna does not teach filling the space around an implant; instead, Muhanna appears to teach filling an implant with such a gel. Consequently, the reason suggested for combining the teachings of Muhanna with the structure shown in the Ralph patents does not appear to be supported by the respective disclosures of those references and it is therefore requested that the rejection of claims 20-21 be reconsidered and withdrawn.

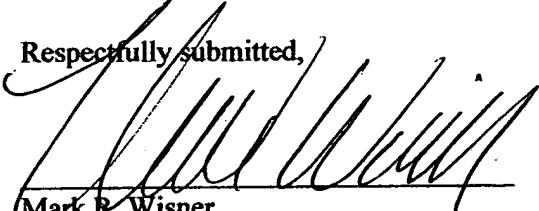
Claim 26 recites that while the implant is comprised of an incompressible material, the insert is comprised of a compressible material to provide cushioning and there is no disclosure in Ralph or Muhanna of an implant comprised of compressible and incompressible materials. There does not even appear to be a teaching or suggestion in these references that the intervertebral implant could be comprised of two different materials, much less a material that is compressible to provide cushioning. Applicant is mindful of the allegation in the Action as to the rigidity of the material comprising the implant, but again, patentability is not assessed in a vacuum such that the context and use of an invention is a factor in determining whether an invention is patentable and as noted above, the fact that metal is not completely rigid and could be compressed (if enough force is exerted on it) is of little relevance in the context of the present invention. For these reasons, reconsideration and withdrawal of the rejection of claim 26 is respectfully requested.

Claims 22-23, also rejected under §103, are dependent on allowable claim 19 and are therefore likewise allowable. Reconsideration and withdrawal of the rejection of claims 22-23 is respectfully requested.

The §103 rejection of claim 30 over the combination of the Sertich and Pisharodi '926 patents is likewise traversed. Contrary to the allegation in the Action and as set out above, Sertich does not teach the use of a compressible insert, nor would the combination of the Pisharodi '926 device with the Sertich device constitute the mere substitution of one type of peg for another as alleged at the bottom of page 5 of the Action. Nor does Sertich teach the "releasing" of any of the structure that is disclosed in that reference as alleged on page 5 of the Action. In short, it is respectfully submitted that the Action fails to establish a proper *prima facie* showing of the obviousness of the differences between the method claimed in claim 30 and the combination of the Pisharodi '926 and Sertich patents, and it is respectfully requested that the §103 rejection of that claim be reconsidered and withdrawn.

Entry of the above amendments, consideration of the remarks set out herein, allowance of the claims, and passage of the application to issuance are all respectfully requested. In the unforeseen event that there are questions and/or issues yet to be answered in this application, it is respectfully requested that Applicant's Attorney be contacted at the address and phone number set out below.

Respectfully submitted,



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